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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,181	07/26/2001	Felix Theeuwes	DURE-023	9651

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EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 01/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/917,181	THEEUWES ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,6-14,17-22,24,25 and 29-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *24,25 and 32* is/are allowed.

6)☒ Claim(s) *1,2,4,6-13,18-22,29 and 30* is/are rejected.

7)☒ Claim(s) *14, 17 and 31* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the two outlets (claim 17) and two lumens (claim 18) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. (It is not clear in the drawings and in the specification where the two outlets and two lumens are located. For example, specification, page 37, line 4, states that outlet is located at (24), and Figures 8A and 8B, shows only one reference number (24).)

Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of

any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 6-13, 18-20, 22 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolinsky et al. 5,087,244.

Wolinksy discloses an elongate body (10) comprising a proximal end defining an inlet, and a distal end defining an outlet, the elongate body defining a lumen in the elongate body, said lumen extending between the proximal and distal ends;

and a diffuser element (16) operatively associated with the elongate body so as to define a diffusion space (i.e., space within element 16), wherein the elongate body distal end outlet is disposed in and in fluid communication with the diffusion space, and wherein the diffusion space is drug-permeable and water-permeable to provide for dilution of a drug in the diffusion space. (The device is capable of providing for dilution of a drug since, for example, if fluid pressure from the source of medicine is discontinued, some fluid from the patient's body may entered element 16.)

As to claim 2, the diffuser element (16) comprises a semipermeable membrane, a microporous membrane or an ion exchange membrane. (The element 16 has minute holes (29) that is considered semipermeable since it allows through medicine or fluid but not substances that are larger than the size of the holes.)

As to claim 4, the distal outlet of the elongate body is defined by an exit orifice (20) of a drug delivery device and the diffuser element (16) is considered a cap in which the exit orifice is disposed since element (16) is at the distal end of elongate body.

As to claim 6, the diffusion space is defined by an outer wall of the elongate body (10) and an inner wall of the diffuser element (16), (see lumen at and near 20, Figure 2.)

As to claim 7, said diffuser element (16) envelops at least a portion of said elongate body (10), see Figure 2.

As to claim 8, the diffuser element is microporous, (column 4, lines 1-2.)

As to claim 9, the diffuser element is considered a dense membrane, (see column 5, lines 22-24, and lines 49-51.)

As to claim 10, the diffuser element is an ion-exchange membrane, (column 4, lines 1-2) since the holes (29) are capable of allowing an exchange of ions.

As to claim 11, said diffuser element distal end extends distally beyond the elongate body distal end, see Figure 2.

As to claim 12, the diffuser element distal is ring-shaped element, see Figure 2.

As to claim 13, the diffuser element is selectively permeable to water (column 4, lines 3-5.)

As to claim 18, the elongate body defines at least two lumens within the elongate body (18 and 26).

As to claims 19 and 24, the elongate body lumen is adapted for delivery of agent at a low volume rate, (column 4, lines 19-24.)

As to claim 20, the device is operably attached to a drug delivery reservoir, (column 5, lines 25-26.)

As to claim 22, the drug is capable of being delivered in microliter or submicroliter quantities per day (column 4, lines 3-5.)

As to claim 29, the diffuser element comprises a polymeric film, (column 3, lines 47-49.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolinsky et al., 5,087,244.

Wolinsky discloses the invention substantially as claimed (see above).

Wolinsky discloses that the "aggregate flow area defined by the holes 29 is selected so that under the general range of inflation pressures expected, the liquid flow through the holes will be very low, weeping in nature, and will not exceed a

predetermined maximum flow rate in atmosphere. Although the foregoing configuration of holes is believed to be satisfactory for a wide range, and possibly most, if not all, medications or drugs to be delivered, it is possible that certain medications or drubs [believed by Examiner to be a misspelling for 'drugs'] may have viscosity and flow characteristics as might require modifications to the holes" (column 4, lines 19-29.)

Wolinsky however does not teach that the diffuser element has a Diffusion Coefficient value in the range between 4.1 x 10-6 and 3.3 x 10-5 ug/cm/sec. However, it would have been obvious to form the diffuser element in which the holes' size and spacing is selected such that it has the specific Diffusion Coefficient as claimed, since Wolinsky teaches that medications may have viscosity and flow characteristics that might require modifications to the holes.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolinsky et al., 5,087,244, in view of Aoki et al., 6,113,915.

Wolinsky discloses the invention substantially as claimed (see above). Wolinsky teaches a catheter for delivery drugs to a body member having a lumen (column 2, lines 49-53.) However, Wolinksky does not disclose that the catheter contains Baclofen.

Aoki teaches use of a small catheter to deliver baclofen to treat spasticity since the intrathecal space is generally wide enough to accommodate a small catheter (column 2, lines 41-45.) It would have been obvious to use the Wolinsky catheter to deliver baclofen to treat spasticity since the intrathecal space is generally wide enough to accommodate a small catheter, as taught by Aoki.

Response to Arguments

Applicant's arguments with respect to the above claims have been considered but are not persuasive.

With respect to the drawing objections, Applicant argues that the single outlet (24) in Applicant's drawings is merely indicative of a device containing one or more lumen and thus outlets, and the skilled artisan, when reading the claims and specification while viewing the drawings, will be able to understand that simple partitioning or duplication of the exemplified structure found in any one of Figures 108 provides a multiple lumen/outlet configuration. This is found to be unpersuasive since it is not clear as to the structure and location of the claimed two outlets or lumens. For example, it is not clear as to whether the lumens are annular lumens or tubular lumens. It is also not clear as to where the two outlets are located. Are they located at the distal end or on the sides of the elongate body? It is also not clear as to whether the two lumens are side by side, or one within the other as is the case of an annular lumen. It is also not clear as to whether or not both the lumens extend to the distal end of the elongate body.

Applicant also argues on pages 10-12 that the Wolinsky device cannot provide for dilution of drug and that operation of the Wolinsky device actually precludes the device from providing dilution of drug since the holes only allow passage of fluid medicament from within the device when maintained under pressure. In response, Examiner emphasizes that a recitation of the intended use of the claimed invention must

result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In this case, the above rejected claims are directed to a device, rather than a method of using. The device of Wolinsky meets the device claims since it is capable of performing the intended use, that is, of diluting drug. Passage of fluid from a patient's body into the Wolinsky device depends on the difference in fluid pressure from within the device and the fluid pressure of the fluid in a patient's body.

Applicant also argues on page 13 that the forming the diffuser element to have the diffusion coefficient as claimed would render the Wolinsky device unsuitable for its intended purpose. Examiner disagrees and reasserts that modification of the holes in the Wolinsky device encompasses holes having the diffusion coefficient as claimed, the modification of the holes being necessary due to different viscosity and flow characteristics of different medications as taught by Wolinsky.

Allowable Subject Matter

Claims 24, 25 and 32 are allowed.

Claims 14, 17, and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.

Christopher L. Chin

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PRIMARY EXAMINER
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1/17/05